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Comments submitted to
NOSB Certification, Accreditation and Compliance Committee

regarding
NOSB Recommendation on Peer Review Panel
(version dated July 8, 2005)

By Lynn S. Coody, M.S.

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Thank you for the opportunity to submit comments on the recommendation written by the NOSB Certification, Accreditation and Compliance Committee on the National Organic Program's Peer Review Panel (PRP). I appreciate the careful consideration of the issue and applaud the Committee for moving forward with establishment of this important body required by the Organic Foods Production Act.

Since I have commented numerous times before the NOSB, you probably know that my work within the organic industry focuses on accreditation issues. My business provides assistance to certifiers in meeting the requirements of accreditation programs such as the National Organic Program, ISO Guide 65, and IFOAM. I am also a member of the OTA's Accreditation Subcommittee and an auditor of accreditation systems for the National Institute of Standards and Technology (NIST). Based on my experience with accreditation-related issues in the organic industry, I respectfully submit the comments detailed below.

PART I: COMMENTS ON THE COMMITTEE'S RECOMMENDATION

Point #1: Changing Definition of "Peer Review Panel" in §205.2 of the Rule

Committee's Recommendation

The definition of "peer review panel" in 205.2 be changed to read:
"Peer review/auditing organization: An organization, agency or group engaged in accreditation of agencies similar to NOP, with appropriate understanding of accreditation procedures related

to organic production and handling methods and who assist in evaluating the accreditation procedures and policies of the National Organic Program."

Proposed Amendment to the Committee's Recommendation
The definition of "Peer Review Panel" in 205.2 be changed to read: "Peer Review Panel: A panel established by the Secretary, comprised of individuals, agencies, or groups engaged in accreditation of programs similar to NOP, that has appropriate experience with the accreditation procedures used to assess bodies that certify organic production and handling operations. The Peer Review Panel assists in evaluating the accreditation procedures and policies as implemented by the National Organic Program."

Explanation of the Proposed Revision
In concept, I agree with the Committee's recommendation to amend the definition of the term "Peer Review Panel". The committee's recommended changes bring the definition in line with the manner in which the term "peer review" is commonly understood in the field of quality assessment. In addition, I concur with the need to have the §205.2 and §205.509 of the Final Rule congruent with respect to the structure and function of the peer review body.

I suggest retaining the term "Peer Review Panel" over the Committee's suggestion to change the term to "Peer review/auditing organization". I favor the original term because it is used in the Organic Foods Production Act (OFPA), the legislation that provides authorization and support for the PRP. I'm also partial to this term because it is flexible enough to retain the concept of allowing individuals as well an agency or group to serve on the PRP, as is provided for in the current definition of the term in the Final Rule.

The intent of my proposal to amend portions of the Committee's text is to strengthen the definition by requiring the peer review body to have specific experience with the accreditation systems used in the organic world. Although procedures used to perform accreditation are similar in function, many accreditation systems focus on assessment of manufacturing and laboratory environments, which are significantly different from organic agricultural systems. When Peer Reviewers are analyzing quality system documentation, operator files, and especially when they are performing witness audits in farmers' fields, specific experience with organic production practices, as well as the systems organic certifiers use to assess these practices, is extremely important to ensure full consideration of all aspects of the accreditation system being assessed.

My proposed revision also clarifies that the accreditation process is assessing certification bodies, as opposed to a direct assessment of production and handling operations. I think it is important to clarify that accreditation and certification are distinctly different activities.

Point #2: Rule Change vs. Guidance

As stated above, I concur with the Committee that it is necessary to change the definition of the term "Peer Review Panel" used in the Final Rule. In contrast, I suggest that the amended language of the Committee's recommendation be presented as guidance used to clarify NOP's process for peer review instead of putting it forward as a regulatory change.

I do not see any reason to change the text of §205.509 as it serves both the NOP and the public interest by establishing a system for transparent evaluation and continuous improvement of the NOP's accreditation program. In addition, in my opinion, the text of §205.509 is clearly stated and it adequately presents the central features of the oversight system envisioned by the drafters of OFPA in that: it requires permanent establishment of the review panel, it specifically requires annual review of the accreditation program, and it references ISO 61 and Subpart F of the Rule as the bases for assessment.

Point #3: Audit cycle

Committee's Recommendation
Section 205.509 of the Final Rule be changed to read:
"The administrator shall contract with a credible, independent, peer auditing/review organization engaged in accreditation of agencies similar to NOP to conduct a review of NOP accreditation procedures and performance on at least a three-year cycle.

Proposed Amendment to the Committee's Recommendation
The administrator shall contract with a credible, independent, Peer Review Panel engaged in accreditation of agencies similar to NOP to conduct a review of NOP accreditation procedures and performance at least at every two years.

Add the following requirement: In the period between its regular site audits, NOP will provide the Peer Review Panel with information needed for regular surveillance activities, on a timeframe established by the panel.

Comment
I think the Committee's recommendation for the NOP to contract a credible and independent PRP is a practical way to meet the requirements for peer review contained in OFPA. Assessing an accreditation system requires significant time and effort and the assessor must have specialized training in the field of quality assessment. This is a task that clearly requires funding and formal contracting arrangements.

However, I am concerned that the 3-year period between peer review audits, as allowed by the Committee's recommendation, is too long. When quality assessment systems allow more than one year between site audits, the lengthening of the interval between on-site assessments typically depends on the proven stability of the accreditation agency[1]. It is common for audits to be conducted annually until the agency has well-established accreditation procedures as well as quality system documentation. As recent audits by the American National Standards Institute (ANSI) and the Office of the Inspector General (OIG) have concluded, NOP does not fully meet either of these conditions at this time.

Therefore, I suggest that the Committee change its recommendation to require that site audits be conducted no more than every two years apart and that the audits be augmented with a system of regular surveillance activities throughout this biennial cycle. Surveillance is a common practice of agencies that grant recognition to accreditation bodies—it is a method of tracking an accreditation body's activities in the period between full audits. Regular surveillance of elements

[1] An example of this principle may be found in §§7.11.a. & b. of ISO 17011.

such as the results of internal audits, management reviews, complaints, appeals, and implementation of corrective actions would increase confidence that the NOP's accreditation program is in compliance with Subpart F of the Rule and ISO 17011.[2]

Point #4: Selection of the Peer Review Panel

Committee's Recommendation
The selection of the auditing/review organization will be made by the Administrator with input from NOSB.

Comment
Although I recognize that the NOSB's role is limited by its status as an Advisory Committee, I concur that the NOSB's input in the selection of the Peer Review Panel is extremely important. I think the NOSB's participation will be essential in ensuring that the assessment is conducted by a body that has appropriate experience with the accreditation procedures used to assess bodies that certify organic production and handling operations. In my opinion, the Administrator's careful consideration of the NOSB's recommendation will increase public confidence that the assessment body selected is truly credible and independent.

Point #5: Scope of the Peer Review Assessment

Committee's Recommendation
The scope of the review shall be to evaluate all aspects of the NOP accreditation program including those outlined in subpart F of these regulations and in ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions.

Proposed Amendment to the Committee's Recommendation
The scope of the review shall be to evaluate all aspects of the NOP accreditation program against the requirements outlined in both subpart F of these regulations and in ISO/IEC 17011:2004, General requirements for accreditation bodies accrediting conformity assessment bodies, (or the corresponding section of any future regulations replacing these documents).

Comment
I fully support the Committee's specific references to the requirements of both Subpart F of the Rule and ISO standards for accreditation bodies, in light of the fact that the audit report resulting from the NOP's first external audit by the American National Standards Institute (ANSI) indicates that the audit did not use Subpart F of the Final Rule as a basis for the assessment. However, I do recommend a revision of the Committee's text to clarify this point as my reading of the current text is that it could be construed to imply that there is some portion of the NOP accreditation program included in ISO/IEC Guide 61.

Please note that the reference to ISO Guide 61 is outdated; as mentioned briefly earlier in these comments, ISO Guide 61 has been recently superseded by ISO 17011. This is explained the foreword to the new ISO standard:

[2] Note that ISO 17011 succeeds ISO Guide 61, which is the assessment standard referenced in §205.509 of the Final Rule.

"The first edition of ISO/IEC 17011 cancels and replaces ISO/IEC Guide 58, ISO/IEC Guide 61 and ISO/IEC/TR 17010. Many accreditation bodies requested this revision because, for quite similar activities, they have had to comply with three sets of largely repetitious but slightly differing, requirements for the same attributes."

In addition, I suggest eliminating the Committee's text requiring assessment of the NOP's accreditation decisions. I do not believe this point must be specifically stated because reviewing the decision-making process, as well as its outcome, is a routine part of an assessment against the standards referenced in the Committee's recommendation.

Point #6: Responding to Audit Findings

Committee's Recommendation
The NOP will respond to findings within three months of receiving the completed audit report.

Proposed Amendment to the Committee's Recommendation
The NOP will respond, in writing, to each of the findings documented in the assessor's report, and make both the audit report and the NOP's response available to the public within three months of receiving the completed audit report from the assessment body.

Comment
I strongly recommend that a requirement for a formal, written response from the NOP regarding the audit findings be coupled with a requirement for public transparency of the audit results, as well as the NOP's responses to them. I agree with the Committee that a three-month period is sufficient for the NOP to develop its responses to audit findings and make them public. Note that NOP-accredited certifiers are usually allowed 60 days to submit their responses to the USDA with respect to findings related to their accreditation by NOP.

Point #7: Taking Corrective Actions

Committee's Recommendation
The review and NOP response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities in regard to the NOP. The NOSB will review the NOP response and work together with NOP staff to construct a sufficiency assessment and ensure there is constructive discussion and agreement on substantive issues. *The audit/review, NOP response, and cooperative review of the audit and response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities in regard to the NOP.*

Proposed Amendment to the Committee's Recommendation
The review and NOP response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities for the NOP, with special emphasis on correction of all of the NOP's deficiencies with each of the standards used during the assessment (Subpart F and ISO/IEC 17011) within timelines to be agreed upon by the NOP and NOSB. The NOSB will review the NOP response and work together with NOP staff to construct a sufficiency assessment and ensure there is constructive discussion and agreement on substantive issues. NOP will make regular reports, to the Administrator and the to NOSB, to provide updates on the corrective actions taken by the agency to bring all aspects of the NOP accreditation program into compliance with both standards in a timely manner.

Comment
A formal process for accreditation agencies to take action to come into compliance with all provisions of ISO/IEC 17011 is required in §5.5 of this ISO standard, as shown by the excerpt below:

> ***5.5 Nonconformities and corrective actions***
> *The accreditation body shall establish procedures for the identification and management of nonconformities in its own operations. The accreditation body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall cover the following:*
>
> *a) identifying nonconformities (e.g. from complaints and internal audits);*
>
> *b) determining the causes of nonconformity;*
>
> *c) correcting nonconformities;*
>
> *d) evaluating the need for actions to ensure that nonconformities do not recur;*
>
> *e) determining the actions needed and implementing them in a timely manner;*
>
> *f) recording the results of actions taken;*
>
> *g) reviewing the effectiveness of corrective actions.*

PART II: SUMMARY OF PROPOSED CHANGES

Proposed changes to the definition in §205.2:

The definition of "Peer Review Panel" in 205.2 be changed to read: "Peer Review Panel: A panel established by the Secretary, comprised of individuals, agencies, or groups engaged in accreditation of programs similar to NOP, that has appropriate experience with the accreditation procedures used to assess bodies that certify organic production and handling operations. The Peer Review Panel assists in evaluating the accreditation procedures and policies as implemented by the National Organic Program."

Proposed changes to the body of the text of the Committee's Recommendation:

The administrator shall contract with a credible, independent, Peer Review Panel engaged in accreditation of agencies similar to NOP to conduct a review of NOP accreditation procedures and performance at least at every two years.

(a) The selection of the Peer Review Panel will be made by the Administrator with input from NOSB.

(b) The scope of the review shall be to evaluate all aspects of the NOP accreditation program against the requirements outlined in both subpart F of these regulations and in ISO/IEC 17011:2004, General requirements for accreditation bodies accrediting conformity

assessment bodies, (or the corresponding section of any future regulations replacing these documents).

(c) The NOP will respond, in writing, to each of the findings documented in the assessor's report, and make both the audit report and the NOP's response available to the public within three months of receiving the completed audit report from the assessment body. The review and NOP response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities for the NOP, with special emphasis on correction of all of the NOP's deficiencies with each of the standards used during the assessment (Subpart F and ISO/IEC 17011) within timelines to be agreed upon by the NOP and NOSB.

(d) The NOSB will review the NOP response and work together with NOP staff to construct a sufficiency assessment and ensure there is constructive discussion and agreement on substantive issues.

(e) NOP will make regular reports, to the Administrator and the to NOSB, to provide updates on the corrective actions taken by the agency to bring all aspects of the NOP accreditation program into compliance with both standards in a timely manner.

(f) In the period between its regular site audits, NOP will provide the Peer Review Panel with information needed for regular surveillance activities, on a timeframe established by the panel.

PART III: CONCLUSION

I would like to thank the NOSB Certification, Accreditation and Compliance Committee for its work on the important issues related to the Peer Review Panel. The accreditation program is a vital element in creating a credible system for regulating the organic industry in the United States. When managed in compliance with the standards mandated by law and regulation, the accreditation system fosters public confidence in organic products domestically and also plays a fundamental role in establishing favorable trade relationships with foreign governments.